DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Dr. David C. Greenspan
Vice President & Chief Technology Officer
NovaMin Technology, Incorporated
13709 Progress Boulevard #23
Alachua, Florida 32615

Re: K040858
Trade/Device Name: Oralief™ Therapy for Sensitive Teeth
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 18,2004
Received: August 19,2004

Dear Dr. Greenspan:

This letter corrects our substantially equivalent letter of September 02,2004, regarding the classification of your device which was incorrectly identified as "unclassified."

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent, for the indications for use stated in the enclosure, to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR **Part** 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D
STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K040858

Device Name: Oralief™ Therapy for Sensitive Teeth

INDICATIONS FOR USE:

Provides rapid and continual relief from tooth hypersensitivity-due to cold, heat, acids, sweets, or contact through its action of the occlusion of dentin tubules.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040858

Prescription Use X OR (Per 21 CFR 801.109) Over-The-Counter Use ____

SEP - 2 2004

K040858

SECTION E
510(K) SUMMARY

1. SUBMITTER INFORMATION:

Name:	NovaMin Technology, Inc.
Address:	13709 Progress Blvd., #23 Alachua, Florida 32615 USA
Phone:	(386) 418-1551
Facsimile:	(386) 418-1465
Contact:	David C. Greenspan, Ph.D.

Preparation Date:	April 1, 2004

2. DEVICE NOMENCLATURE:

Trade Name:	Oralief™ Therapy for Sensitive Teeth
Common Name:	Dentifrice; Toothpaste
Classification Name:	Agent, Polishing, Abrasive, Oral Cavity

3. LEGALLY MARKETED PREDICATE DEVICE:

Device Name:	Butler GUM® Prophylaxis Paste with NovaMin®
510(k) Number:	K024343
Applicant:	USBiomaterials Corporation

4. DEVICE DESCRIPTION:

Oralief™ Therapy for Sensitive Teeth incorporates NovaMin® as its active ingredient. The unique brushing regimen and NovaMin®-containing formulation provide rapid and continual relief from tooth sensitivity. NovaMin® (calcium sodium phosphosilicate) is composed of elements that occur naturally in the body (Ca, Na, Si, P, and O). When exposed to an aqueous environment, NovaMin® rapidly releases mineral-building ions, allowing it to relieve from sensitivity by physically occluding dentin tubules. Within a short period of time, essentially all of the NovaMin® reacts to form a mineral layer which is chemically and structurally similar to natural tooth mineral.

5. INTENDED USE:

Clinical studies have shown that Oralief™ provides rapid and continual relief from tooth hypersensitivity due to cold, heat, acids, sweets, or contact through its action of the occlusion of dentin tubules.

6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of Oralief™ and Butler GUM® Prophylaxis Paste with NovaMin® are very similar. Both devices are designed to relieve hypersensitivity associated with exposed dentin by the deposition of a calcium phosphate layer onto the tooth surface. Both devices use NovaMin® to produce a calcium phosphate layer that occludes dentinal tubules and blocks hydrodynamic flow. The primary difference between the two devices is that Oralief™ supplies the calcium and phosphate ions on a daily basis for two weeks, followed by a once a week maintenance brushing for twenty-four weeks, whereas Butler GUM® Prophylaxis Paste with NovaMin® supplies the ions once every professional tooth cleaning. Oralief™ is intended to be distributed by the professional in the dental office for home use by the patient, whereas Butler GUM® Prophylaxis Paste with NovaMin® is applied by the hygienist in the dental office. In addition, there are some differences in the proportion of the ingredients in the two products.

7. SAFETY AND PERFORMANCE DATA:

Many different biocompatibility tests have been performed on NovaMin®, the active ingredient in Oralief™. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of Oralief™ was evaluated using an *in vitro* dentin block model. The results indicate that Oralief™ occludes a significantly greater number of tubules when compared to controls.

A double-blinded, two-arm parallel group study was conducted to assess the efficacy of a 7.5% w/w NovaMin®-containing toothpaste formulation in the reduction of tooth hypersensitivity. The study protocol was approved by the Ethics Committee at the Dental School of the University of Bologna, Italy. Two measures of sensitivity were used in the study; a metered air blast (one second duration) and cold water (3 ml at 4°C) delivered from a syringe. The time between measures on a given tooth was at least 3 minutes. Subjects were instructed to brush their teeth in their usual manner for one minute, brushing no more than a total of two times per day for two weeks. At the two-week appointment, patients were instructed to use the product only once a week for two additional weeks. A total of 20 patients were enrolled in the study, 10 in each group. A total of 48 sensitive teeth were measured in the NovaMin® toothpaste group and 42 teeth in the placebo group. There were no adverse events reported during the study. All patients completed the course of treatment.

A 2 (treatment) x 5 (time periods) repeated-measures ANOVA was conducted on the VAS score averaged across the cold water and air pressure methods. The results showed that there were significant effects of treatment (NovaMin® was statistically better at reducing sensitivity than placebo, $p < .001$) and that the effects were statistically significant over the time periods as well ($p < .001$). *Post hoc* tests showed that there were no differences between the test and placebo group at baseline (NovaMin® mean VAS = 6.68 ±0.88, Placebo = 6.37 ± 1.05), but that the test group was statistically better at each time point than the placebo (NovaMin® VAS at week 2 = 2.85 ± 1.52, versus Placebo VAS = 5.91 ±0.92, $p < 0.01$). The test group showed statistical decline in VAS score at each time point, and the placebo only showed a statistical decrease at the 3-week ($p < .021$) and 4-week ($p < .017$) time periods versus baseline. The results of this study demonstrated that the 7.5% w/w NovaMin®-containing formulation provided rapid and continual relief from tooth hypersensitivity.

8. CONCLUSIONS:

Oralief™ is considered to be substantially equivalent to the legally marketed predicate device, Butler GUM® Prophylaxis Paste with NovaMin® (K024343). The provided clinical study and biocompatibility data demonstrate the safety and efficacy of Oralief™ for the intended use.